

REMARKS

In the Office Action mailed September 29, 2009, the Examiner rejected claims 1-5, 7, 8, 10, 14-18, 20, 21, 23 and 27-50. By way of the foregoing amendments and the markings to show changes, applicants have amended claims 1-5, 8, 10, 14-18, 21, 23, 27-45, 47, and 49. Claim 51 is new. Claims 1-5, 7-8, 10, 14-18, 20-21, 23 and 27-51 are currently pending. The foregoing amendments are taken in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicant would otherwise be entitled in view of the prior art.

Further, by the present amendment, it does not follow that the amended claims have become so perfect in their description that no one could devise an equivalent. After amendment, as before, limitations in the ability to describe the present invention in language in the patent claims naturally prevent the Applicants from capturing every nuance of the invention or describing with complete precision the range of its novelty or every possible equivalent. See, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 62 USPQ2d 1705 (2002). Accordingly, the foregoing amendments are made specifically in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicants would otherwise be entitled.

Rejection Under 35 U.S.C. §112

Claims 1-5, 7, 8, 10, 14-18, 20, 21, 23 and 34-39 have been rejected under 35 U.S.C. §112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention. The claims have been amended to reflect the presence of cells in both device and method claims. Thus, the volume ratios claimed do in fact define the invention.

Claims 1-5, 7, 8, 10, 14-18, 20, 21, 23 and 28-50 (which is assumed to mean 27-50) have been rejected under 35 U.S.C. §112, second paragraph as being indefinite. As stated above, the claims have been amended to reflect the presence of cells in both device and method claims. Further, the references to "final composition" and "parts" have been removed and the claim language clarified. The claims have also been amended to indicate that the volume of compounds includes all compounds pre-loaded into the device, not limited to only the anticoagulant and fixative. The weight per volume measurements in the claims have also been clarified to specify that the measurements are per unit of preloaded compound.

Rejection Under 35 U.S.C. §103

Claims 1-4, 7, 8, 10, 14-17, 20, 21, 23 and 27-50 have been rejected under 35 U.S.C. §103 as being unpatentable over Ryan in view of Camiener, Glover and Louderback. At page 7 of the Office Action dated September 29, 2009, the Examiner states that "in the interest of compact prosecution, the claims are interpreted as being drawn to a collection device comprising an anticoagulant and diazolidinyl urea, wherein the device has at least a partial vacuum inside." Applicant understands this to indicate that the Examiner has not taken the claimed volume ratios into account in analyzing the claims in view of the cited references. Applicant believes that this "compact prosecution" process is not proper and fails to satisfy the Examiner's burden to set forth the difference or differences in the claim over the applied references as required by 35 U.S.C. §103 and MPEP 706.02(j). As further support for this understanding, the Examiner has failed to identify why the claimed volume ratios would be obvious in view of the cited references. Further, at page 10 of the Office Action the Examiner further states that "ratio arguments are not germane to the patentability of the device". In an effort to rectify this issue, Applicant respectfully submits that the device and method claims as amended include the addition of cells. Thus, limitations regarding the ratio of compound volume to the combined volume of the compounds and cells are now germane to the patentability of the devices as methods claimed. Applicant therefore submits that the claims as amended to include proper references to volume ratios (as required by the Examiner) are not taught by the cited prior art.

The Examiner has also failed to satisfy her burden to demonstrate that Ryan teaches the claimed invention, and in particular the Examiner has not shown where Ryan teaches the elements of a concentrated form of DU/IDU having the ratio of compound volume to combined volume of compound and cells claimed in the present application. Applicant therefore respectfully submits that the claims are patentable in view of Ryan.

In further support of Applicant's assertion of patentability, the commercial product embodied by the claims of the present application has experienced substantial market success as the only blood collection tube providing enhanced simplicity of blood draw and storage by providing direct blood draw capability and requiring only minute concentrated amounts of cell stabilizers. By employment of high concentrations and small amounts of fixative, the Applicant submits that the results realized from the invention herein are unexpected in that they have gone against the conventional wisdom that a small amount of fixative is able to sufficiently disperse within a sample for effective stabilization. The results are further unexpected in that the high concentrations of fixative do not shock the stabilized cells (which would irreversibly harm

the cell structure) as would be expected from such high concentrations. This objective evidence of nonobviousness further supports patentability.

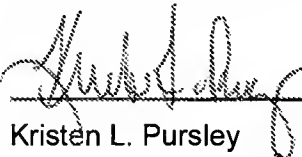
CONCLUSIONS

In view of Applicants' amendments and remarks, the Examiner's rejections are believed to be rendered moot. Accordingly, Applicants submit that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 292-2920.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Respectfully submitted,

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